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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA**

Richard Di Donato, et al.,

No. CV-16-00302-PHX-NVW

**Plaintiffs,**

## ORDER

V.

Insys Therapeutics Incorporated, et al.,

### Defendants.

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1        Before the Court is a Motion to Dismiss filed by defendants Insys Therapeutics  
 2 Incorporated (“Insys”), Michael L. Babich, Darryl S. Baker, John N. Kapoor, and Alec  
 3 Burlakoff (collectively “Defendants”). (Doc. 85.) Clark Miller (“Plaintiff”) is the lead  
 4 plaintiff for the proposed plaintiff class in this action. He filed a response (Doc. 87), and  
 5 Defendants filed a reply (Doc. 95). The Court now considers these and all accompanying  
 6 briefing.

7

## 8        **I. FACTUAL ALLEGATIONS**

9        For this motion to dismiss, the following facts from Plaintiff’s second amended  
 10 complaint are assumed to be true.

### 11        **A. Insys and Subsys**

12        Defendant Insys is a publicly traded pharmaceutical company headquartered in  
 13 Arizona that makes and sells pain management drugs. (Doc. 77, ¶ 1.) Defendants  
 14 Babich, Baker, Kapoor, and Burlakoff all served as high level executives at Insys during  
 15 the relevant class period, between 2014 and 2016. (Doc. 77, ¶¶ 30-33.)

16        Since 2013, roughly 98% of Insys’s net revenue has come from a product called  
 17 Subsys, an under-the-tongue fentanyl spray designed to treat cancer pain in adult patients  
 18 already taking opioid pain medication (known as “opioid-tolerant adults”). (Doc. 77,  
 19 ¶ 2.) The power of fentanyl cannot be overstated. The highly addictive drug is 80-100  
 20 times stronger than morphine and 40-50 times more potent than heroin. The Drug  
 21 Enforcement Agency has classified fentanyl as a “Schedule II” substance under the  
 22 Controlled Substances Act. (Doc. 77, ¶ 73.)

23        The Food and Drug Administration approved Subsys in 2012 only for opioid-  
 24 tolerant adults and only for what is known as “breakthrough” cancer pain, intense  
 25 episodes amid otherwise-steady levels of pain. (Doc. 77, ¶ 6; Doc. 85 at 5.) The FDA  
 26 also required that any healthcare professionals prescribing, dispensing, or distributing  
 27 Subsys must first enroll in a program called the Transmucosal Immediate-Release  
 28 Fentanyl Risk Evaluation and Mitigation Strategy Access Program (the “Access

1 Program”). (*Id.*) Among other things, the Access Program enabled Insys to monitor all  
 2 sales of Subsys. (*Id.*) Additional FDA regulations prohibit marketing approved drugs for  
 3 “off-label” uses, i.e., any uses other than the ones for which the drug was actually  
 4 approved. Subsys therefore could not be lawfully marketed for anything other than  
 5 breakthrough cancer pain treatment in opioid-tolerant adults. (Doc. 77, ¶ 10.)

6 In addition, a federal anti-kickback law prohibits anyone from paying a doctor to  
 7 order a good or service reimbursed by a federal healthcare program. (*Id.*) See 42 U.S.C.  
 8 § 1320a-7(b)(2). According to Insys’s own SEC filings, sales of Subsys at all relevant  
 9 times “depend[ed] in significant part on the coverage and reimbursement policies of  
 10 third-party payers, including government payers such as Medicare and Medicaid, and  
 11 private health insurers.” (Doc. 77, ¶ 9.) Coverage decisions would depend in large part  
 12 on “pharmacy benefit managers,” entities within insurance companies that maintain lists  
 13 of covered drugs, contract with pharmacies, negotiate prices with drug manufacturers,  
 14 and process prescription drug claims. (Doc. 77, ¶ 93.)

15 Because of these tight regulations, only specialty pharmacies can distribute the  
 16 drug. The resulting scarcity has fueled skyrocketing prices. Even a small quantity (30  
 17 doses at 100 micrograms per dose) will run a patient about \$1,000 per month. (Doc. 77,  
 18 ¶ 77.) A larger, more potent quantity (240 doses at 1,200 micrograms per dose) can  
 19 exceed \$21,000 per month. (*Id.*)

20 **B. The Underlying Fraud**

21 The class period in this action spans from August 12, 2014, through December 8,  
 22 2016. During that time, Insys reported increasing revenues each quarter and attributed  
 23 most of its upward trajectory to the sale of Subsys. (Doc. 77, ¶ 11.) Company executives  
 24 publicly attributed the drug’s success to vigorous marketing efforts and the company’s  
 25 diligent negotiations with pharmacy benefit managers, third-party payers, and insurers.  
 26 (Doc. 77, ¶ 12.) The company made no mention of unlawful practices actually taking  
 27 place. Defendants at different times said (or were reported to have said) that Insys was  
 28 “only selling a breakthrough cancer pain drug,” that “no one at Insys wants to see anyone

1 taking [Subsys] for anything other than cancer pain,” and that Insys was “committed to  
 2 complying with the laws governing [Subsys’s] sales, marketing and promotional  
 3 practices.” (Doc. 77, ¶ 99.) The defendants told investors that they “properly  
 4 communicate with all major [insurance] plans and the [pharmacy benefit managers] to  
 5 ensure proper access for Subsys.” (Doc. 77, ¶ 211.)

6 According to the complaint, however, Insys was actually raking in large profits  
 7 because of extensive criminal fraud: the company had made a practice of paying doctors  
 8 bribes and kickbacks in exchange for prescribing Subsys off-label, which boosted the  
 9 company’s sales and, consequently, its stock price. (Doc. 77, ¶¶ 14, 201-08.) Many of  
 10 these doctors have been federally indicted beginning as early as 2012, and several have  
 11 pled guilty to violations of federal anti-kickback statutes. (Doc. 77, ¶¶ 15, 158.)

12 Central to the fraud was Insys’s “Insurance Reimbursement Center,” a unit the  
 13 company created ostensibly “to interact with third-party payers to obtain prior  
 14 authorization and insurance coverage for invariably expensive Subsys prescriptions.”<sup>1</sup>  
 15 (Doc. 77, ¶ 16.) To ensure coverage for Subsys, employees of the Insurance  
 16 Reimbursement Center would falsify patient diagnoses, lie to insurance companies using  
 17 canned scripts written by Insys executives, and even pose as employees of the prescribing  
 18 doctors. (*Id.*) Insys paid employees bonuses for doing these things, and for securing  
 19 more Subsys prescriptions. (Doc. 77, ¶ 20.) During the class period, Insys informed  
 20 investors that the Insurance Reimbursement Center existed but disclosed nothing else  
 21 beyond its advertised purpose of working with insurers to cover Subsys. The company  
 22 did not disclose any of the fraudulent conduct in which the Insurance Reimbursement  
 23 Center was actually engaging. (Doc. 77, ¶ 212.)

24 The fraud also extended to what Insys called its “speaker series,” which it passed  
 25 off as a series of educational talks by doctors invited (and compensated) to speak about  
 26 the benefits of Subsys. (Doc. 77, ¶¶ 14, 101.) In reality, however, these events were

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27  
 28 <sup>1</sup> At oral argument, Plaintiff clarified that the unit went by other names at different  
 points in time, among them the “Prior Authorization Unit.”

1 usually nothing more than social gatherings devoid of any substantive content used as  
 2 vehicles to funnel cash payments to prescribing physicians. (Doc. 77, ¶ 149.) Insys sales  
 3 representatives sometimes even forged attendance sheet signatures to make it appear as  
 4 though the speakers had given presentations before an audience. (Doc. 77, ¶ 164.)  
 5 Defendant Burlakoff said of the speakers hired by Insys, “[T]hey do not need to be good  
 6 speakers, they need to write a lot of [Subsys prescriptions].” (Doc. 77, ¶ 14.) Insys’s  
 7 stock continued to climb as all this was going on.

8 Despite these actions, Insys maintained that it was “taking market share from other  
 9 competing . . . products and expanding the usage of Subsys for [breakthrough cancer  
 10 pain] by building awareness among oncologists.” (Doc. 77, ¶ 111.) The company touted  
 11 its “very unique programs within the oncology setting” for increasing sales, all while  
 12 executives were specifically steering sales representatives away from doctors who  
 13 prescribed the drug for breakthrough cancer pain. (Doc. 77, ¶¶ 111-12.) Less than 1% of  
 14 Subsys prescriptions were actually written by oncologists. (Doc. 77, ¶ 112.) Instead  
 15 Insys pushed its own sales force to cajole doctors into prescribing Subsys for off-label  
 16 uses, pressuring salespeople to use aggressive tactics and paying them meager base  
 17 salaries with commissions tethered to their success generating prescriptions. (Doc. 77,  
 18 ¶¶ 132-33, 139.)

### 19           **C. Public Statements**

20           From the beginning of the class period, Insys made a number of public statements  
 21 regarding its revenue figures and stock price. Plaintiff points to the following statements  
 22 in the second amended complaint:

- 23       1) On August 12, 2014, the first day of the class period, Babich stated in a press  
           24 release that a 200% sales growth compared to the same time the previous year was  
           25 “largely driven by the successful execution of our Subsys strategy.” (Doc. 77,  
           26 ¶ 251.)
- 27       2) On a conference call with investors the same day, Babich stated, among other  
           28 things, “We believe the success to date of Subsys is the result of a clinically

1 superior product, coupled with the focused market penetration strategy,” and  
 2 “[t]he majority of patients have access to Subsys through their insurance plans.”  
 3 (Doc. 77, ¶ 252.) The company later made materially similar statements regarding  
 4 their earnings the next two quarters. (Doc. 77, ¶¶ 261, 267.) Babich also told  
 5 investors, “[W]e continue to properly communicate with all the major plans and  
 6 the [pharmacy benefit managers] to ensure proper access for Subsys.” (Doc. 77,  
 7 ¶ 253.)

- 8 3) In its Form 10-Q for the second quarter of 2014, Insys stated, “The increase in  
  9 Subsys revenue is primarily as a result of increased prescriptions and change in  
 10 mix of prescribed dosages as Subsys was a relatively new product during the three  
 11 months [and six months] ended June 30, 2012 and also price increases in January  
 12 2014 and April 2014. . . .” (Doc. 77, ¶ 254.)
- 13 4) On November 11, 2014, Insys issued a third quarter press release reporting  
  14 “another strong quarter, in which our revenue and gross profit doubled largely  
  15 driven by the continued, successful execution of our Subsys strategy.” (Doc. 77,  
  16 ¶ 260.)
- 17 5) In a conference call on the same day, Babich stated, “We continue to proactively  
  18 work with managed care providers to ensure coverage for our patient population.  
  19 We maintain Tier 3 coverage under nearly all major commercial plans, and the  
  20 majority of patients have access to Subsys through their insurance plans.” (Doc.  
  21 77, ¶ 261.)
- 22 6) The next day, in its Form 10-Q for the third quarter of 2014, the company  
  23 reported, “[T]he increase in Subsys revenue is primarily as a result of increased  
  24 prescriptions and change in mix of prescribed dosages as Subsys was a relatively  
  25 new product during the three months ended September 30, 2013 and also price  
  26 increases in January 2014 and April 2014.” (Doc. 77, ¶ 262.)
- 27 7) On a March 3, 2015 conference call with analysts, Babich said of the company’s  
  28 high fourth quarter earnings,

We keep hitting new highs in the number of new doctors that we activate on a weekly basis. We have some very unique programs within the oncology setting that we continue to execute on and any growth that we see in this overall [drug] class is specifically coming from Subsys.

(Doc. 77, ¶ 268.)

- 8) Also on March 3, 2015, Insys filed a Form 10-K for the fiscal year 2014. Among other things, the company asserted,

Subsys has been, and will likely continue to be, subject to these restrictions and impediments from third-party payers, administrative patient support assistance, in large part through our patient services hub, which provides administrative support assistance to help patients work with their insurance companies.

(Doc. 77, ¶ 269.) The company made similar statements amid a similar growth in revenue throughout the class period. (Doc. 77, ¶¶ 284, 293, 302.)

- 9) The Form 10-K also stated, “[W]e commercialize Subsys through a cost-efficient commercial organization utilizing an incentive-based sales model similar to that employed by” some of its competitors. (Doc. 77, ¶ 271.)
  - 10) Among “key factors” in its growth, Insys identified the following:

taking market share from other competing . . . products and expanding the usage of Subsys for [breakthrough cancer pain] by building awareness among oncologists of its rapid onset of action, improved bioavailability, most complete range of dosage strengths and ease of administration relative to other [fentanyl] products.

(Doc. 77, ¶ 272.)

- 11) On April 24, 2015, the Southern Investigative Reporting Foundation published an article quoting Burlakoff as saying,

[T]here is a very, very easy way to get fired on your first day at this company,...and that is to mention selling off-label. We are only selling a breakthrough cancer pain drug. That's all we want to address with a doctor. You don't run a unit at a company like this by cutting corners. . . . I can say that no one at Insys wants to see anyone taking [Subsys] for anything other than cancer pain.

(Doc. 77, ¶¶ 278-79.)<sup>2</sup>

- 12) On May 7, 2015, Insys issued a press release regarding its earnings in the first quarter of 2015, which stated, "Insys had another strong quarter driven by our twelfth consecutive quarter of Subsys sales growth." (Doc. 77, ¶ 281.)
- 13) Babich conducted a conference call with analysts and investors the same day in which he stated, "[T]hree years post-launch our Subsys business remains healthy and continues to grow. This clearly demonstrates that a better product can succeed in a crowded playing field, and we believe there is even more opportunity for Subsys on the horizon." (Doc. 77, ¶ 282.)
- 14) In its Form 10-Q for the first quarter of 2015, Insys stated, "The increase in Subsys revenue is primarily as a result of increased prescriptions and change in mix of prescribed dosages and also price increases in January 2014, April 2014, July 2014, and January 2015." (Doc. 77, ¶ 283.) The company made similar statements regarding revenue increases during the second quarter of that year several months later. (Doc. 77, ¶ 292.)
- 15) On August 6, 2015, Insys issued a press release addressing, among other things, a then-recent settlement with the Oregon Department of Justice regarding allegations that it promoted Subsys illegally. (Doc. 77, ¶¶ 289, 322.) In the press release, Insys wrote that it was "committed to complying with laws governing its sales, marketing and promotional practices and has implemented a comprehensive

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<sup>2</sup> Plaintiff's complaint is replete with added emphasis in the form of italics, underlining, and bold text—and sometimes all three at once. The Court here, as elsewhere, silently omits that emphasis, as it is immaterial to deciding this motion.

1 compliance program based on the elements of an effective compliance program  
 2 and industry practices.” (Doc. 77, ¶ 289.)

3 16) That same day, in a conference call with investors and analysts, Babich stated,  
 4 “[T]he Company continues to be committed to complying with laws governing in  
 5 sales, marketing, and promotional practices. And then we’ve implemented a  
 6 comprehensive compliance program based on the elements of an effective  
 7 compliance program and industry practices.” (Doc. 77, ¶ 291.)

8 17) On November 5, 2015, in a conference call with investors and analysts pertaining  
 9 to Insys’s high quarterly earnings, Kapoor stated that patients “like [Subsys]  
 10 because it helps them, it helps their lives. It’s not that they get addicted to it, as  
 11 some people imply. It’s a product that they – it helps their lives and that’s why the  
 12 product gained the market share and will continue to gain market share.” (Doc.  
 13 77, ¶ 297.)

14 18) In the same call, Kapoor said, “[W]e only call on [risk evaluation and mitigation  
 15 strategy] . . . doctors,<sup>3</sup> and so – once we get to 50% [of the market share], further  
 16 growth is going to be slower than it has been in the past and that’s why we have  
 17 accelerated the development of Subsys in other indications.” (Doc. 77, ¶ 298.)  
 18 Kapoor also stated that Babich’s sudden resignation as CEO was not related to  
 19 investigations of Insys, attributing it instead to Babich’s desire to spend time with  
 20 his family “and pursue other interests.” (Doc. 77, ¶ 299.)

21 19) In its Form 10-Q pertaining to the third quarter of 2015, the company  
 22 characterized an increase in Subsys revenue as “primarily as a result of a 31%  
 23 increase in shipments to pharmaceutical wholesalers for the three months ended  
 24 September 30, 2015 as compared to the three months ended September 30, 2014,”  
 25 and “a 26% increase in net sales price, which was impacted by price increases in

26  
 27       <sup>3</sup> “Risk Evaluation and Mitigation Strategy” doctors are “doctors who have  
 28 already qualified to prescribe Subsys and other [transmucosal immediate-release fentanyl  
 drugs] under the FDA’s [Risk Evaluation and Mitigation Strategy] program.” (Doc. 85 at  
 30.) See § I(A) above.

1       July 2014, January 2015 and July 2015, combined with changes in mix of  
 2 prescribed dosages and changes in provisions for wholesaler discounts, patient  
 3 discounts, rebates and returns.” (Doc. 77, ¶ 300.) The company made a similar  
 4 statement about Subsys’s increased revenue over the nine month period ending  
 5 September 30, 2015. (Doc. 77, ¶ 301.)

6 20) Regarding criminal allegations made against one specific doctor, the Form 10-Q  
 7 stated that “we have taken a number of remedial actions and implemented  
 8 enhancements to the Company’s compliance controls regarding relationships with  
 9 health care providers. We will continue to assess these matters to ensure we have  
 10 an effective compliance program.” (Doc. 77, ¶ 303.)

11 21) In a publicly released statement on November 23, 2015, Insys stated:

12           Insys has a compliance program in place with protocols that are  
 13 designed to ensure its sales and marketing practices comply with  
 14 applicable laws. . . . Insys believes that existing data strongly support  
 15 that prescribing decisions have been driven primarily by the clinical  
 16 attributes of Subsys and its market share gains have come from  
 17 patients and [healthcare providers] switching to Subsys from other  
 18 [fentanyl] products.

19           (Doc. 77, ¶ 309.)

20 22) On January 25, 2016, in response to a Southern Investigative Reporting  
 21 Foundation article detailing fraud allegations against Insys, Insys issued a  
 22 statement saying, “Insys rejects the recent media reports’ account of the  
 23 Company’s practices as misleading and unreliable, especially in light of the biased  
 24 agenda held by the individuals who made these misrepresentations.” (Doc. 77,  
 25 ¶ 313.) The statement additionally said, “Insys requires its Patient Services Center  
 26 personnel undergo specific training on applicable laws and regulations and  
 27 continues to strive to comply with applicable laws and regulations through its  
 28 compliance policies and procedures.” (*Id.*)

1                   **D. News of Criminal Fraud Allegations**

2                   Revelations of Insys's alleged fraud soon began trickling into the public sphere.  
 3                   Insys itself disclosed in a September 12, 2014 SEC filing that it had received a subpoena  
 4                   from the United States Attorney's Office for the District of Massachusetts, seeking  
 5                   documents related to the company's sales and marketing of Subsys. (Doc. 77, ¶ 315.)  
 6                   Two months later, on November 27, the New York Times published an article detailing  
 7                   allegations of the company's kickback scheme. (Doc. 77, ¶ 316.) Insys's stock fell  
 8                   8.58% over the next several days. (*Id.*) Similarly, an April 24, 2015 article published by  
 9                   the Southern Investigative Reporting Foundation provided further details of the  
 10                  company's alleged criminal fraud. (Doc. 77, ¶¶ 317-18.) Over the next three days the  
 11                  company's stock fell 9.61%. (*Id.*) Other news items preceded similar drops: a May 20,  
 12                  2015 federal indictment of two doctors accused of conspiring to unlawfully prescribe  
 13                  Subsys (triggering a 4.43% drop), a June 23, 2015 New York Times article disclosing the  
 14                  guilty plea of a Connecticut nurse charged with accepting kickbacks (triggering a 12.64%  
 15                  drop), a November 4, 2015 CNBC article detailing the Oregon Department of Justice's  
 16                  investigation into Insys (triggering an 8.50% drop), a December 3, 2015 article by the  
 17                  Southern Investigative Reporting Foundation detailing the alleged Insurance  
 18                  Reimbursement Center fraud (triggering an 18.54% drop), and a January 25, 2016 article  
 19                  by the Southern Investigative Reporting Foundation expanding on the Insurance  
 20                  Reimbursement Center's practices (triggering a 4.72% drop). (Doc. 77, ¶¶ 19-20, 319-  
 21                  20, 323-24, 326-27, 330).

22                  On April 11, 2016, Insys issued a press release disclosing quarterly revenues of  
 23                  between \$61 million and \$62 million, about \$25 million below previous projections,  
 24                  triggering a 19.37% drop in the company's stock price. (Doc. 77, ¶¶ 21, 332.) Analysts  
 25                  attributed the fall to the company's lower-than-expected sales and revenues for the first  
 26                  quarter of 2016. (Doc. 77, ¶ 333.)

27                  On December 8, 2016, the last day of the class period, the federal government  
 28                  announced the arrest and criminal indictment of defendants Babich, Burlakoff, and other

1 former Insys executives. (Doc. 77, ¶ 23.) The indictment, unsealed and made available  
 2 to the public on December 8, accused Babich and Burlakoff of leading “a nationwide  
 3 conspiracy to bribe medical practitioners to unnecessarily prescribe a fentanyl-based pain  
 4 medication and defraud healthcare insurers.” (Doc. 77, ¶ 343.) By the end of December  
 5 8, Insys’s stock had fallen 11.87% compared to its closing price the previous day. (Doc.  
 6 77, ¶ 344.) Since the start of the class period, Insys’s stock dropped from \$44.92 per  
 7 share to \$9.43. (Doc. 77, ¶ 24.)

8           **E. Plaintiffs**

9           The proposed class of plaintiffs in this case purchased Insys stock during the class  
 10 period. (Doc. 77, ¶ 28.) Lead plaintiff Clark Miller made his first purchase of Insys  
 11 stock, 250 shares for \$59.64 each, on May 19, 2015. (Doc. 34-1 at 3.) Less than a month  
 12 later, on June 8, 2015, Miller’s nominal stockholdings doubled to 500 shares after a stock  
 13 split with no additional stock purchase. (*Id.*) On July 8, 2015, Miller sold all 500 shares  
 14 for \$35.38 per share. (*Id.*) The next day, on July 9, 2015, Miller purchased 4,000 shares  
 15 of Insys stock throughout the day at various prices ranging from \$36.29 to \$36.71 per  
 16 share. (*Id.*)

17           **II. LEGAL STANDARDS**

18           **A. Motion to Dismiss: Securities Fraud Pleading Standards**

19           A complaint alleging securities fraud is subject to the requirements of both Federal  
 20 Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act (PSLRA).  
 21 Under Rule 9(b), a plaintiff alleging fraud “must state with particularity the  
 22 circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). Each and every  
 23 element of securities fraud must meet this pleading standard. *Or. Pub. Emps. Ret. Fund*  
 24 v. *Apollo Gp. Inc.*, 774 F.3d 598, 605 (9th Cir. 2014). In addition, under PSLRA, the  
 25 complaint must “specify each statement alleged to have been misleading, the reason or  
 26 reasons why the statement is misleading, and, if an allegation regarding the statement or  
 27 omission is made on information and belief, the complaint shall state with particularity all  
 28 facts on which that belief is formed.” 15 U.S.C. § 78u-4(b)(1)(B).

1                   **B. Section 10(b) and Rule 10b-5**

2                   Under section 10(b) of the Exchange Act of 1934, it is unlawful “for any  
 3 person . . . [t]o use or employ, in connection with the purchase or sale of any  
 4 security . . . any manipulative or deceptive device or contrivance in contravention of such  
 5 rules and regulations as the [Securities and Exchange] Commission may prescribe[.]” 15  
 6 U.S.C. § 78j(b). *In re Daou Systems, Inc.*, 411 F.3d 1006, 1014 (9th Cir. 2005). SEC  
 7 Rule 10b-5 accordingly provides:

8  
 9                   It shall be unlawful for any person . . .

10                  (a) To employ any device, scheme, or artifice to defraud,

11                  (b) To make any untrue statement of a material fact or to omit to state a  
 12 material fact necessary in order to make the statements made, in light of the  
 13 circumstances under which they were made, not misleading, or

14                  (c) To engage in any act, practice, or course of business which operates or  
 15 would operate as a fraud or deceit upon any person,

16                  in connection with the purchase or sale of any security.

17  
 18                  17 C.F.R. § 240.10b-5. The basic elements of securities fraud are thus sixfold:

19  
 20                  (1) a material misrepresentation or omission; (2) scienter (*i.e.*, a wrongful  
 21 state of mind); (3) a connection between the misrepresentation and the  
 22 purchase or sale of a security; (4) reliance upon the misrepresentation (often  
 23 established in “fraud-on-the-market” cases via a presumption that the price  
 24 of publicly-traded securities reflects all information in the public domain);  
 25 (5) economic loss; and (6) loss causation.

26  
 27                  *Loos v. Immersion Corp.*, 762 F.3d 880, 886-87 (9th Cir. 2014) (citing *Dura*  
 28 *Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005)).

29                   **C. Section 20(a) of the 1934 Exchange Act**

30                  Section 20(a) of the 1934 Exchange Act states that:

1 Every person who, directly or indirectly, controls any person liable under  
 2 any provision of this chapter or of any rule or regulation thereunder shall  
 3 also be liable jointly and severally with and to the same extent as such  
 4 controlled person . . . is liable . . . unless the controlling person acted in  
 5 good faith and did not directly or indirectly induce the act or acts  
 6 constituting the violation or cause of action.

7 15 U.S.C. § 78t(a). Under this “control-person” theory of liability, a defendant employee  
 8 can be held liable for a company’s securities fraud where the plaintiff demonstrates “‘a  
 9 primary violation of federal securities law’ and that ‘the defendant exercised actual power  
 10 or control over the primary violator.’” *In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d  
 11 694, 711 (9th Cir. 2012) (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981,  
 12 990 (9th Cir. 2009)).

### 13 **III. ANALYSIS**

14 Plaintiff’s second amended complaint alleges securities fraud by all Defendants  
 15 under section 10(b) and control-person liability for all defendant individuals (the  
 16 executives only, not Insys itself) under section 20(a). Defendants move to dismiss the  
 17 securities fraud count on grounds that it fails to plead two of the six required elements:  
 18 material misrepresentations or omissions and loss causation. Defendants also seek  
 19 dismissal as to Kapoor and Baker for failing to plead scienter, as well as to Burlakoff for  
 20 failing to establish his statements were made “in connection with” the purchase or sale of  
 21 securities. Finally, Defendants move to dismiss the control-person liability count in its  
 22 entirety.

#### 23 **A. Judicial Notice**

24 Defendants have asked the Court to take judicial notice of fifty-two documents  
 25 that are items referenced in the complaint, public filings, news articles, or undisputedly  
 26 authentic documents made publicly available by the government. (Doc. 81.) Plaintiff  
 27 opposes judicial notice of only one of the documents. The Court will thus take judicial  
 28 notice of the unopposed fifty-one documents, but notes that judicial notice as to court

1 filings made outside of this case is limited to the fact that the filings were made. The  
 2 Court does not (and cannot) take judicial notice of their substantive content as true.

3 Plaintiff's only opposition is to a September 29, 2008 Corporate Integrity  
 4 Agreement between pharmaceutical company Cephalon, Inc. ("Cephalon") and the  
 5 Office of the Inspector General of the United States Department of Health and Human  
 6 Services. (Doc. 88 at 2.) As discussed at oral argument, the Court will take judicial  
 7 notice only of the fact that the agreement exists. The truth or falsity of any of its contents  
 8 cannot be discerned at this stage in the litigation.

9 Plaintiff separately sought judicial notice of three documents filed in other courts.  
 10 Those documents all relate to the indictments and subsequent guilty pleas of healthcare  
 11 providers charged in connection with Insys's alleged fraud. (Doc. 99.) As explained in  
 12 the Court's previous order (Doc. 104), judicial notice has been granted only to the extent  
 13 that such documents were filed in those courts. The Court will not consider their contents  
 14 for this motion.

15 **B. Section 10(b) and Rule 10b-5**

16 **1. Material Misrepresentation or Omission**

17 To make out a claim for securities fraud, a plaintiff "must allege a  
 18 misrepresentation or a misleading omission with particularity and explain why it is  
 19 misleading." *Retail Wholesale & Dep't Store Union Local 338 Retirement Fund v.*  
*Hewlett-Packard Co.*, 845 F.3d 1268, 1274 (9th Cir. 2017). Additionally, "applying an  
 20 objective standard, that misrepresentation or omission must have been material to  
 21 investors." *Id.* Defendants here do not argue that the statements identified in the second  
 22 amended complaint were immaterial. Rather, Defendants move to dismiss on grounds  
 23 that the second amended complaint fails to identify any false or misleading statements  
 24 with sufficient particularity and fails to explain why those statements are false or  
 25 misleading.

26 Rule 10b-5 prohibits only "misleading and untrue statements." *Brody v.*  
*Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). "[A] statement is

1 misleading if it would give a reasonable investor the impression of a state of affairs that  
 2 differs in a material way from the one that actually exists.” *In re Cutera Sec. Litig.*, 610  
 3 F.3d 1103, 1109 (9th Cir. 2010). A statement must be “capable of objective verification”  
 4 in order to be false or misleading. *Retail Wholesale*, 845 F.3d at 1275. This stands in  
 5 contrast to “puffing,” which “concerns expressions of opinion.” *Or. Pub. Emps.*, 774  
 6 F.3d at 606. Qualitative buzzwords such as “good,” “well-regarded,” or other “vague  
 7 statements of optimism” cannot form the basis of a false or misleading statement. *Id.*  
 8 (citing *Cutera*, 610 F.3d at 1111). *See, e.g., Or. Pub. Emps.*, 774 F.3d at 606 (statements  
 9 were neither false nor misleading where defendant company hedged statements about  
 10 revenue growth with “we believe” and cited only “general terms” such as “educational  
 11 content” and “teaching resources”); *Retail Wholesale*, 845 F.3d at 1276 (finding no  
 12 objectively verifiable statements where plaintiff only pointed to defendant company’s  
 13 code of conduct filled with “aspirational” statements not capable of objective  
 14 verification).

15 Beyond merely pleading that the defendant made false or misleading statements,  
 16 for each statement a plaintiff must also “explain why it is misleading.” *Id.* at 1274.  
 17 PSLRA’s pleading requirements cannot be met “by conclusory allegations that a  
 18 company’s class period statements regarding its financial well-being are *per se* false  
 19 based on the plaintiff’s allegations of fraud generally.” *Metzler Inv. GMBH v. Corinthian  
 20 Colleges, Inc.*, 540 F.3d 1049, 1070 (9th Cir. 2008).

21 Defendants point to thirty different statements from the second amended  
 22 complaint concerning Insys’s revenue and profits, or its strategies for marketing Subsys,  
 23 that they contend are insufficiently pled as false or misleading. (Doc. 85 at 14 n.6, 15  
 24 n.8, 16-17, 18 n.11.) For most of them, Plaintiff contends they are false or misleading  
 25 because they were spoken against the backdrop of Insys’s ongoing criminal fraud. But  
 26 *Metzler* precludes that line of argument. *See Metzler*, 540 F.3d at 1070 (holding  
 27 complaint did not sufficiently plead securities fraud where plaintiff alleged public  
 28 statements were false or misleading solely by virtue of defendants’ “fraudulent practices

1 generally along with its failure to make earlier disclosures of regulatory investigations”).  
 2 In light of that broadly applicable principle, most of the statements Plaintiff points to do  
 3 not qualify as false or misleading under Rule 10b-5:

- 4
- 5 1) Paragraphs 251 and 262 point to statements asserting that Subsys’s recent sales  
 6 growth was “largely driven by the successful execution of [Insys’s] Subsys  
 7 strategy.” That statement is essentially true, even if the “strategy” referred to  
 8 involved breaking the law. In any event the term “Subsys strategy” is general  
 9 enough to put the statement outside the scope of what can be misleading or untrue.  
 10 *See Or. Pub. Emps.*, 774 F.3d at 606.
- 11 2) Paragraphs 252 and 261 cite statements by Babich attributing Insys’s success to “a  
 12 clinically superior product, coupled with a focused market penetration strategy.”  
 13 However, the statements begin with “We believe” and are thus sufficiently  
 14 hedged. The second part of each statement goes on to say, “We continue to  
 15 proactively work with managed care providers to ensure coverage for our patient  
 16 population. We maintain Tier 3 coverage under nearly all major insurance plans.  
 17 The majority of patients have access to Subsys through their insurance plans.”  
 18 Plaintiff has not explained how this was false or misleading beyond merely being  
 19 said against the backdrop of ongoing fraud.
- 20 3) Paragraph 253 alleges that Babich said during a conference call that “[w]e  
 21 continue to properly communicate with all the major plans and the [pharmacy  
 22 benefit managers] to ensure proper access for Subsys.” That they were continuing  
 23 “to properly communicate” is neither false nor misleading based on what Plaintiff  
 24 has alleged. That they were doing so “to ensure proper access for Subsys” is too  
 25 vague to be actionable, since it is unclear what “proper access” means.
- 26 4) Paragraphs 254, 283 and 292 assert that “[t]he increase in Subsys revenue is  
 27 primarily as a result of increased prescriptions and change in mix of prescribed  
 28 dosages and also price increases” throughout the year. Paragraphs 300 and 301

1           allege substantively similar statements. Plaintiffs have failed to allege that these  
2           statements are untrue. The only basis on which they could be deemed misleading  
3           is precluded by *Metzler*. *See Metzler*, 540 F.3d at 1070.

- 4) Paragraph 260 points to a press release noting a “strong quarter, in which our  
5           revenue and gross profit doubled largely driven by the continued, successful  
6           execution of our Subsys strategy.” Again, there is no indication the financial  
7           growth figures are untrue. “Successful execution” is a qualitative assessment, and  
8           “Subsys strategy” leaves it too vague as to what the company was asserting.
- 9) Paragraph 261 points to three statements, the first of which begins with “We  
10          believe.” That statement was sufficiently hedged not to qualify as false or  
11          misleading. *See Or. Pub. Emps.*, 774 F.3d at 606. The second statement, that  
12          Insys “continues to proactively work with managed care providers to ensure  
13          coverage” for patients is highly general and neither false nor misleading. Plaintiff  
14          has not challenged as false the third part, that Insys “maintain[s] Tier 3 coverage  
15          under nearly all major commercial plans, and the majority of patients have access  
16          to Subsys through their insurance plans,” beyond being spoken against the  
17          backdrop of the company’s ongoing fraud.
- 18) The statement cited in Paragraph 267 again begins with “We believe.” It is neither  
19          false nor misleading.
- 20) The only questionable part of the statement in paragraphs 269, 284, 293, and 302  
21          is the assertion that Insys “provide[s] administrative reimbursement support  
22          assistance, in large part through our insurance reimbursement support hub, which  
23          provides administrative support assistance to help patients coordinate with their  
24          insurance companies.” While this might be misleading on some level, it is also  
25          highly general and vague. As such it is not actionable.
- 26) Paragraph 270 includes the statement “We believe that physicians and payers will  
27          develop greater familiarity with both the differentiated features of Subsys and the  
28          process to achieve patient access to the product from continued and broader usage

1 of Subsys by their patients. We offer patients a free trial of Subsys to allow for  
2 titration to their effective dose and bridge the prior authorization process.” None  
3 of this is false or misleading based on Plaintiff’s allegations.

- 4 10) Paragraph 271 states that the company “commercialize[s] Subsys through a cost-  
5 efficient commercial organization utilizing an incentive-based sales model similar  
6 to that employed by” some competitors. “Cost-efficient commercial organization”  
7 is too vague to be false or misleading, and the rest of the statement appears to be  
8 true.
- 9 11) Paragraph 282 is a prime example of mere “puffing.” The assertion that Subsys’s  
10 business “remains healthy” is simply qualitative, and that it “continues to grow”  
11 was true. Babich’s assertion that “[t]his clearly demonstrates that a better product  
12 can succeed in a crowded playing field” is qualitative, general, and a mere  
13 expression of general feeling rather than fact. The statement “we believe there is  
14 even more opportunity for Subsys on the horizon” is both hedged and nothing  
15 more than qualitative puffing.
- 16 12) Paragraphs 289 and 291 point to nearly identical statements by Insys and Babich  
17 following the settlement with the Oregon Department of Justice that the company  
18 is “committed to complying with laws governing its sales, marketing and  
19 promotional practices” and has “implemented a comprehensive compliance  
20 program based on the elements of an effective compliance program and industry  
21 practices.” Plaintiff nowhere asserts that Insys had not in fact implemented a  
22 compliance program, however ineffective it might have been. And stating that the  
23 company was “committed” to legal compliance immediately after reaching a  
24 settlement with state regulators is, in that context, too vague to be actionable.
- 25 13) Paragraph 297 points to a conference call in which Kapoor said of Subsys  
26 patients: “They like [Subsys] because it helps them, it helps their lives. It’s not  
27 that they get addicted to it, as some people imply. It’s a product that they – it  
28 helps their lives and that’s why the product gained the market share and will

1 continue to gain market share.” Whether or not these assertions are objectively  
 2 true, nothing alleged in the complaint contradicts them.

- 3 14) Paragraph 298 quotes Kapoor as saying during a conference call, “[W]e only call  
 4 on [Risk Evaluation and Mitigation Strategy] . . . doctors, and so – once we get to  
 5 50%, further growth is going to be slower than it has been in the past and that’s  
 6 why we have accelerated the development of Subsys in other indications.” This  
 7 simply addresses projections about Subsys’s market share. There is nothing false  
 8 or misleading about this statement.
- 9 15) Paragraph 303 points to a statement from the company’s 2015 SEC filings that  
 10 says, “[W]e have taken a number of remedial actions and implemented  
 11 enhancements to the Company’s compliance controls regarding relationships with  
 12 health care providers. We will continue to assess these matters to ensure we have  
 13 an effective compliance program.” Plaintiff nowhere asserts that Insys did not in  
 14 fact take remedial actions or enhance compliance controls when this statement was  
 15 made. In any event the statement is vague and general enough not to qualify as  
 16 false or misleading.
- 17 16) Paragraph 309 points to a statement that says, among other things:
- 18

19 Insys has a compliance program in place with protocols that are  
 20 designed to ensure its sales and marketing practices comply with  
 21 applicable laws. . . . Insys believes that existing data strongly support  
 22 that prescribing decisions have been driven primarily by the clinical  
 23 attributes of Subsys and its market share gains have come from  
 24 patients and [healthcare providers] switching to Subsys from other  
 25 [fentanyl] products.

26 Though both are convoluted, neither of these statements is false or misleading.  
 27 Plaintiff has not alleged that Insys’s compliance protocols, however weak and  
 28 ineffective, were not designed to ensure legal compliance. As for the second  
 statement, it is hedged as the company’s belief and is not actionable.

1       17) Paragraph 313 of the second amended complaint cites an Insys press release  
 2       issued after a January 25, 2016 news article shed light on the company's alleged  
 3       off-label marketing and kickback scheme. The press release stated:

4

5           Insys rejects the recent media reports' [sic] account of the  
 6       Company's practices as misleading and unreliable, especially in light  
 7       of the biased agenda held by the individuals who made these  
 8       misrepresentations. . . . Insys requires its Patient Services Center  
 9       personnel undergo specific training on applicable laws and  
 10      regulations and continues to strive to comply with applicable laws  
 11      and regulations through its compliance policies and procedures.

12

13       This statement specifically asserts that Insys was making efforts to ensure the  
 14       Patient Services Center's practices were lawful. (It is unclear what the "Patient  
 15       Services Center" is, though it might be another name for the Insurance  
 16       Reimbursement Center.) There is reason to think it is therefore false. However, in  
 17       the second amended complaint, Plaintiff only contends it is false because of the  
 18       alleged criminal fraud occurring behind the scenes. (Doc. 77, ¶ 314.) As already  
 19       discussed, that alone cannot ballast a securities fraud pleading. *See Metzler*, 540  
 20      F.3d at 1070.

21

22       None of the above statements meets the pleading requirements of the PSLRA. However,  
 23       three others do:

24

25       1) In the statement cited in paragraph 272, the company's Form 10-K from fiscal  
 26       year 2014, filed on March 3, 2015, points to "taking market share from"  
 27       competitors as key to Subsys's growth. That is neither false nor misleading. But  
 28       the statement goes on to assert that Insys is "expanding the usage of Subsys for  
 29       [breakthrough cancer pain] by building awareness among oncologists of" several  
 30       of the drug's features. However, according to Plaintiff's other allegations,

1 Subsys's growth had little—if anything—to do with breakthrough cancer pain and  
 2 instead depended chiefly on doctors prescribing it off-label to treat conditions such  
 3 as migraines or back pain. Moreover, the company's sales force was deliberately  
 4 avoiding oncologists. The complaint alleges that "Insys sales representatives were  
 5 instructed not only to avoid meeting with oncology doctors and pain  
 6 specialists . . . but to aggressively court healthcare professionals who did not have  
 7 any patients with cancer, much less [breakthrough cancer pain], or who did not  
 8 have any experience in prescribing Schedule II narcotics such as Subsys." (Doc.  
 9 77, ¶ 275.) The complaint also cites multiple alleged statements that further  
 10 support this picture of Insys's actual practices. *See, e.g.*, Doc. 77, ¶ 112 (quoting a  
 11 former sales representative who said that "when she approached her managers  
 12 about reaching out to palliative care facilities to tell them about Subsys, she was  
 13 told not to approach them because 'those patients would die soon anyway and  
 14 couldn't titrate (increase the dosage)'"); ¶ 113 (quoting Burlakoff as instructing  
 15 his sales force, "If I can successfully sell you the [unintelligible] for the  
 16 breakthrough pain, do you have a thousand people in your practice, a thousand  
 17 patients, twelve of them are currently on a rapid-onset opioids [sic]. That leaves  
 18 me with at least five hundred patients [sic] that can go on this drug."). The  
 19 practices alleged in the complaint amount to the complete opposite of "building  
 20 awareness among oncologists." The statement alleged in paragraph 272 therefore  
 21 qualifies as false or misleading.

- 22 2) Most of Babich's March 3, 2015 statement alleged in paragraph 268 is neither  
 23 false nor misleading. Many of the sentences are hedged with "I think." The  
 24 statement "We keep hitting new highs in the number of new doctors that we  
 25 activate on a weekly basis" is again true and not misleading aside from the  
 26 underlying bribe and kickback schemes. But Babich goes on to say, "We have  
 27 some very unique programs within the oncology setting that we continue to  
 28 execute on and any growth that we see in this overall [fentanyl] class is

1 specifically coming from Subsys.” The second part of that is true. The first part,  
 2 however, is again misleading and arguably false in light of the company’s practice  
 3 of steering its sales force away from oncologists altogether. *See Doc. 77, ¶ 275.*  
 4 The specific mention of a physician class they were making a point to avoid  
 5 renders this statement misleading at best and outright false at worst.

6 3) Paragraphs 278 and 279 point to statements by Burlakoff saying of the company’s  
 7 speaker program, “[T]here is a very, very easy way to get fired on your first day at  
 8 this company,...and that is to mention selling off-label. We are only selling a  
 9 breakthrough cancer pain drug. That’s all we want to address with a doctor. . . I  
 10 can say that no one at Insys wants to see anyone taking [Subsys] for anything  
 11 other than cancer pain.” There is no question this is false or misleading.  
 12 However, as discussed below, this statement is quoted in a news article published  
 13 by the Southern Investigative Reporting Foundation, which is not something  
 14 investors would presumptively rely on. So while it meets the PSLRA’s “falsity”  
 15 requirement, it fails under the “in connection with” requirement. *See § III(B)(3)*  
 16 below.

17  
 18 Defendants alternatively offer three blanket contentions as to why none of these  
 19 statements meets the pleading requirements of Rule 9(b) and PSLRA. They are not  
 20 persuasive. First, Defendants contend that none of the statements alleged in the  
 21 complaint could have been misleading because Insys “informed investors of specific law  
 22 enforcement investigations into” the alleged criminal fraud. (Doc. 85 at 15-16.) But  
 23 disclosing an investigation is not the same thing as disclosing specific fraudulent  
 24 practices the company was actually carrying out. Unless Insys disclosed the specific  
 25 practice of discouraging its sales force from pursuing oncologists, the statements  
 26 identified above as false or misleading remain false or misleading.

27 Second, Defendants argue that “in each SEC filing since Insys went public, the  
 28 Company informed investors of the significant risks associated with employee

1 misconduct in marketing and sales practices and other activity.” (Doc. 85 at 16.) In  
 2 particular, Defendants point to specific statements in the company’s SEC filings that  
 3 warn ““employees may engage in misconduct or other improper activities’ including  
 4 ‘intentional failures to comply with FDA regulations”’ as well as ““with federal and state  
 5 healthcare fraud and abuse laws and regulations’ and that ‘[e]mployee misconduct could  
 6 also involve...illegal promotion of a drug product for off-label use.”’ (*Id.* (quoting Doc.  
 7 81-2 at 44-49).) But hypothetical disclaimers such as these do not insulate companies  
 8 from all fraud liability. The Ninth Circuit has rejected the mollifying power of abstract  
 9 risk warnings that fail to “alert[] the reader that some of these risks may already have  
 10 come to fruition.” *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 986 (9th Cir.  
 11 2008). *See also Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1181 (9th Cir.  
 12 2009) (rejecting warning issued in company’s Form 10-Q of risk that products may be  
 13 subject to product liability claims only “in the abstract, with no indication that the risk  
 14 ‘may already have come to fruition’”). Here as well, Insys’s repeated disclosures offered  
 15 no indication that its employees were currently breaking the law.

16 Third, Defendants argue that some of their statements are covered by PSLRA’s  
 17 “safe harbor” provision. (Doc. 85 at 19-20.) PSLRA protects from securities fraud  
 18 liability any “forward-looking statement” made under several different circumstances,  
 19 two of which are relevant here. First, a forward-looking statement is protected if it is  
 20 “identified as a forward-looking statement, and is accompanied by meaningful cautionary  
 21 statements identifying important factors that could cause actual results to differ materially  
 22 from those in the forward-looking statement.” 15 U.S.C. § 78u-5(c)(1)(A)(i). Second,  
 23 a forward-looking statement is protected if “the plaintiff fails to prove” that, if made by a  
 24 “natural person,” the statement “was made with actual knowledge by that person that the  
 25 statement was false or misleading.” 15 U.S.C. § 78u-5(c)(1)(B)(i). Defendants point to  
 26 part of the statement cited in paragraph 268 of the second amended complaint, in which  
 27 Babich discusses the company’s market share of Subsys’s class of drugs. (Doc. 85 at 20.)  
 28 As discussed, this part of Babich’s statement is neither false nor misleading, so the Court

1 need not decide whether it is forward-looking. (The part of the cited statement asserting  
 2 that Insys has programs in which they work with oncologists is misleading, as discussed  
 3 above.) That is the only specific statement from the second amended complaint to which  
 4 Defendants point. Defendants broadly contend that “[t]his and other forward-looking  
 5 statements are in the ‘safe harbor’” (Doc. 85 at 20), yet they cite no other specific  
 6 statements for which they believe dismissal is warranted. The Court is not at liberty to  
 7 guess which other statements they had in mind. Defendants have not established that  
 8 PSLRA’s safe harbor provision warrants dismissal of the complaint or any part of it.

9       **2. Scienter**

10       Under PSLRA, a securities fraud complaint must “state with particularity facts  
 11 giving rise to a strong inference that the defendant acted with the required state of mind.”  
 12 15 U.S.C. § 78u-4(b)(2)(A). The plaintiff must show “scienter,” i.e., that any false or  
 13 misleading statements were made “either intentionally or with deliberate recklessness.”  
 14 *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009). “Deliberate  
 15 recklessness” is “an *extreme* departure from the standards of ordinary care...which  
 16 presents a danger of misleading buyers or sellers that is either known to the defendant or  
 17 is so *obvious* that the actor must have been aware of it.” *Schueneman v. Arena Pharm., Inc.*,  
 18 840 F.3d 698, 705 (9th Cir. 2016) (emphasis in original). “The inquiry . . . is  
 19 whether *all* of the facts alleged, taken collectively, give rise to a strong inference of  
 20 scienter, not whether any individual allegation, scrutinized in isolation, meets that  
 21 standard.” *Tellabs Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-23 (2007)  
 22 (emphasis in original). *But see VeriFone Holdings*, 704 F.3d at 703 (permitting courts to  
 23 examine specific allegations of scienter before looking at all allegations taken together  
 24 “so long as [the analysis] does not unduly focus on the weakness of individual allegations  
 25 to the exclusion of the whole picture”). “The inference that the defendant acted with  
 26 scienter need not be irrefutable . . . or even the most plausible of competing inferences”  
 27 but must merely be “cogent and at least as compelling as any opposing inference one  
 28

1 could draw from the facts alleged.” *Tellabs Inc.*, 551 U.S at 324 (internal quotation  
 2 marks omitted).

3 Under certain circumstances, one may infer that corporate officers had scienter by  
 4 virtue of their “knowledge of the critical core operation of their companies.” *Police*  
 5 *Retirement System*, 759 F.3d at 1062. Even without particularized allegations, this “core  
 6 operations” theory of scienter may apply “in rare circumstances where the nature of the  
 7 relevant fact is of such prominence that it would be absurd to suggest that management  
 8 was without knowledge of the matter.” *Id.* A plaintiff can produce either “specific  
 9 admissions by one or more corporate executives of detailed involvement in the minutia of  
 10 a company’s operations, such as data monitoring,” or “witness accounts demonstrating  
 11 that executives had actual involvement in creating false reports.” *Id.* Compare *Daou*,  
 12 411 F.3d at 1022-23 (finding inference of scienter where complaint alleged specific  
 13 executives “personally directed [the company’s] recognition of revenue, financial  
 14 reporting and public statements” and directed practices of fraudulently reporting revenue  
 15 figures), and *Nursing Home Pension Fund, Local 144 v. Oracle Corp.*, 380 F.3d 1226,  
 16 1231 (9th Cir. 2004) (finding strong inference of scienter where executives had  
 17 consolidated database with real time sales information and admitted to knowing “exactly  
 18 how much we have sold in the last hour around the world”), with *Lipton v. Pathogenesis*  
 19 *Corp.*, 284 F.3d 1027, 1036 (9th Cir. 2002) (finding no inference of scienter where  
 20 complaint alleged “merely in conclusory terms that defendants had access to internal data  
 21 demonstrating a decline in sales” of a prescription drug and did not “allege with  
 22 particularity any specific information showing that prescription data informed defendants  
 23 that patient demand for [the drug] was flat”).

24 Defendants contend the second amended complaint does not adequately plead  
 25 scienter as to Kapoor and Baker. The Court considers their arguments as to each one in  
 26 turn.  
 27  
 28

1                   **a. Kapoor**

2                   The statements identified in paragraph 272 of the second amended complaint  
 3 come from Insys's Form 10-K from the fiscal year 2014, which was signed by Babich,  
 4 Baker, and Kapoor. (Doc. 77, ¶¶ 269, 272.) Because Kapoor signed the filing, the  
 5 contents constitute his statements, and the complaint alleges sufficient facts giving rise to  
 6 a strong inference of scienter, i.e., that he either knew they were false or misleading or  
 7 exhibited deliberate recklessness in making them. Kapoor had direct contact with some  
 8 of the doctors who were targets of the company's bribes and kickbacks. The complaint  
 9 alleges that a member of the Insys sales force, also the son of a physician sought after by  
 10 Insys to write off-label Subsys prescriptions, made reference on multiple occasions to  
 11 positive meetings between his father and Kapoor. (Doc. 77, ¶¶ 123-24.) In addition,  
 12 Kapoor attended a dinner at Ruth's Chris Steak House in Mobile, Alabama, where he and  
 13 other Insys executives sealed an agreement to sell Subsys directly to a pharmacy owned  
 14 by those doctors for a cut rate. (Doc. 77, ¶ 194.) Finally, many of the company's  
 15 allegedly fraudulent "speaker series" events took place at locations of a restaurant owned  
 16 by Kapoor. (Doc. 77, ¶ 148.)

17                  Each of these individually raises at least a plausible inference of scienter. One  
 18 could reasonably infer from each one that Kapoor knew Insys was running a fraudulent  
 19 speaker series and paying doctors bribes and kickbacks to increase prescriptions of  
 20 Subsys. One could even infer that Kapoor himself was leading the operation. Of course  
 21 one could also plausibly infer that Kapoor made or facilitated contact with doctors absent  
 22 any such knowledge. But the test is not whether scienter is the only plausible inference;  
 23 it must simply be "cogent and at least as compelling as any opposing inference one could  
 24 draw from the facts alleged." *Tellabs Inc.*, 551 U.S. at 324. Especially taken altogether,  
 25 the inference is strong and compelling: Kapoor interacted (or facilitated interactions) with  
 26 doctors who do not treat cancer pain and did so in environments reasonably interpreted as  
 27 designed to sell them on Subsys.

28

1       Scienter is also plausible on the “core operations” theory. Kapoor served in one  
 2 high-level leadership role or another throughout the class period: he was Insys’s co-  
 3 founder, served as Executive Chairman of the Board of Directors throughout much of the  
 4 class period, and served as acting president and CEO of Insys from November 5, 2015,  
 5 until the end of the class period. (Doc. 77, ¶ 32.) Revenue from Subsys accounted for  
 6 roughly 98% of Insys’s total revenue since 2014. (Doc. 77, ¶ 363.) At a conference in  
 7 December of 2015, Kapoor himself stated that he and other Insys officials “have a  
 8 meeting everyday [sic] . . . looking at what happened yesterday. I can tell you how many  
 9 [prescriptions] we did yesterday. And we do that every single day, because Subsys is so  
 10 important to us.” (Doc. 77, ¶ 349.) Even though Kapoor was only acting CEO from  
 11 November 2015 on, it is implausible that even as executive chairman of its board of  
 12 directors he would not have known 98% of the company’s revenue was coming from  
 13 Subsys prescriptions. And it is absurd to think he would not have known that Subsys’s  
 14 revenue, which was glaringly high among comparable fentanyl products, was being  
 15 driven by fraud. Even on the core operations theory, Plaintiff has sufficiently pled  
 16 scienter as to Kapoor.

17                  **b. Baker**

18       Baker, too, signed the Form 10-K containing the statements identified in  
 19 paragraph 272 of the second amended complaint. As a result, the statement is fairly  
 20 attributed to him as much as it is to Babich and Kapoor.

21       The complaint, however, contains less evidence of Baker’s state of mind. Plaintiff  
 22 first points to the fact that Baker was CFO of Insys during the class period and signed not  
 23 only the Form 10-K but each and every one of the company’s SEC filings. (*See, e.g.*,  
 24 Doc. 77, ¶¶ 254, 262, 269, 283, 292, 300.) In those filings, Plaintiff argues, Baker “made  
 25 detailed factual statements” about Subsys revenues “while misrepresenting and omitting  
 26 the sources of those revenues.” (Doc. 87 at 22.) Plaintiff also points to Defendants’  
 27 collective access to information, such as sales figures from the Access Program and  
 28 Kapoor’s general statement that high-level executives closely monitored Subsys

1 prescriptions, as warranting an inference of scienter as to Baker specifically. (Doc. 87 at  
 2 20-21.) Finally, Plaintiff at oral argument pointed out that because Insys paid a glaringly  
 3 high amount to a small number of Subsys prescribers, those payments—not to mention  
 4 the high commissions Insys gave to its otherwise-low-paid sales reps—almost certainly  
 5 required approval by Baker and at the very least were subject to his review on the  
 6 company's books. *See Doc. 77, ¶ 374.*

7 All of that suffices to meet the threshold for giving rise to a plausible inference of  
 8 Baker's scienter. Either way, scienter can be inferred on the core operations theory: as  
 9 the company's CFO, it is absurd to think Baker knew about Subsys's anomalous market  
 10 dominance but did not know how the company had pulled off the feat when he signed on  
 11 to the company's SEC filings. The complaint has adequately alleged that he did.

12 **3. Connection with Purchase or Sale of a Security**

13 To make out a claim of securities fraud, a plaintiff must also show the alleged  
 14 fraud "somehow touches upon or has some nexus with any securities transaction." *S.E.C.*  
 15 *v. Rana Research, Inc.*, 8 F.3d 1358, 1361-62 (9th Cir. 1993) (internal quotation marks  
 16 omitted). "Where the fraud alleged involves public dissemination in a document such as  
 17 a press release, annual report, investment prospectus or other such document on which an  
 18 investor would presumably rely, the 'in connection with' requirement is generally met by  
 19 proof of the means of dissemination and the materiality of the misrepresentation or  
 20 omission." *Id.* at 1362. The crux of the inquiry is whether "assertions are made . . . in a  
 21 manner reasonably calculated to influence the investing public." *Id.*

22 Defendants only challenge this requirement as to Burlakoff and argue that, among  
 23 other things, the only statements of his cited in the second amended complaint "are not  
 24 actionable because Plaintiff does not allege that they were made in a publication 'on  
 25 which an investor would presumptively rely,'" such as "an SEC filing, press release, call  
 26 with analysts or a financial news publication," or were "intended to influence the  
 27 investing public." (Doc. 85 at 32.) Defendants are correct.

28

Burlakoff's only allegedly false statements identified in the complaint are quotations from a Southern Investigative Reporting Foundation article from April of 2015, which quoted him as saying, "We are only selling a breakthrough cancer pain drug. That's all we want to address with a doctor. . . . I can say that no one at Insys wants to see anyone taking [Subsys] for anything other than cancer pain." (Doc. 77, ¶¶ 278-79.) The complaint does not say when, where, or to whom Burlakoff made this statement, only that it was published in the article. The kinds of statements courts have found to satisfy the "in connection with" requirement are typically documents directly targeted to investors or the investment community—and at the very least documents produced by the defendants themselves. *See, e.g., McGann v. Ernst & Young*, 102 F.3d 390, 397 (9th Cir. 1996) (audit report that would be included in SEC filings); *S.E.C. v. Retail Pro, Inc.*, 673 F. Supp. 2d 1108, 1132 (S.D. Cal. 2009) (annual and quarterly reports, press releases, and conference calls); *S.E.C. v. Trabulse*, 526 F. Supp. 2d 1001, 1006 (N.D. Cal. 2007) (account statements and newsletters sent directly to investors); *S.E.C. v. Pirate Investor LLC*, 580 F.3d 233, 250-51 (4th Cir. 2009) (collecting cases and concluding email message with fraudulent insider information met "in connection with" requirement where email authors "certainly should not have been shocked to learn that their fraudulent statements induced securities transactions").

The Southern Investigative Reporting Foundation news article at issue here is a far cry from these examples and certainly not the kind of document on which investors would presumably rely. But even if it were, there is no allegation that Burlakoff wrote or published it, only that it contained a quote attributed to him. The published quote might correctly reflect what Burlakoff said, but it might also contain inaccuracies over which he had no control. Since he did not produce the article, and since it is not something upon which investors would presumably rely, the statement from the Southern Investigative Reporting Foundation attributed to Burlakoff fails to meet the "in connection with" requirement. All claims against him under Section 10(b) are dismissed.

28

1           **4. Loss Causation**

2           Loss causation is the requirement that a securities fraud plaintiff “must  
 3 demonstrate that the defendant’s deceptive conduct caused [the plaintiff’s] claimed  
 4 economic loss.” *Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1209 (9th Cir. 2016). *See* 15  
 5 U.S.C. § 78u-4(b)(4) (“[T]he plaintiff shall have the burden of proving that the act or  
 6 omission of the defendant alleged to violate this chapter caused the loss for which the  
 7 plaintiff seeks to recover damages.”). Loss causation is established where “the market  
 8 learns of a defendant’s fraudulent act or practice, the market reacts to the fraudulent act  
 9 or practice, and a plaintiff suffers a loss as a result of the market’s reaction.” *In re Oracle*  
 10 *Corp. Sec. Litig.*, 627 F.3d 376, 392 (9th Cir. 2010).<sup>4</sup>

11          A plaintiff can establish that a market became aware of fraud by showing  
 12 “corrective disclosures,” news or announcements to investors that revealed the  
 13 company’s prior misstatements to have been false or misleading. *Lloyd*, 811 F.3d at  
 14 1209. The revelation may be direct or require steps of inference. *See, e.g., Cement &*  
 15 *Concrete Workers Dist. Council Pension Fund v. Hewlett Packard Co.*, 964 F. Supp. 2d  
 16 1128, 1146 (N.D. Cal. 2013) (finding loss causation adequately pled where CEO’s  
 17 resignation amid misconduct allegations preceded stock drop, giving rise to plausible  
 18 inference that market treated resignation as disclosure of fraud); *Daou*, 411 F.3d at 1026  
 19 (loss causation adequately pled where defendant company’s below-expected revenue  
 20 figures preceded sharp drops in stock price).

21          Disclosures can come in many forms but must occur under the right circumstances  
 22 to establish loss causation. News of an investigation, for example, only informs the

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24          <sup>4</sup> Some courts have noted a potential inconsistency in the Ninth Circuit’s loss  
 25 causation legal standard as it has developed over time. *See Smilovits v. First Solar Inc.*,  
 26 119 F. Supp. 3d 978, 986-92 (D. Ariz. 2015) (Campbell, J.) (observing two lines of cases,  
 27 one finding loss causation only where market learns of underlying fraud, the other where  
 28 fraud causes plaintiff’s loss regardless of market’s knowledge). Because the Ninth  
 Circuit has not resolved this question, the Court here applies the standard from the  
 circuit’s most recent cases, which require a plaintiff to show the market actually learned  
 of the alleged fraud that caused its securities to decline in value. *See Oracle*, 627 F.3d at  
 392; *Metzler*, 540 F.3d at 1063. However, it is the Court’s judgment that the motion here  
 would come out the same way under either approach.

1 market of fraud “if the complaint also alleged a subsequent corrective disclosure by the  
 2 defendant.” *Lloyd*, 811 F.3d at 1210. *Accord Loos*, 762 F.3d at 890 (holding that “the  
 3 announcement of an investigation, without more, is insufficient to establish loss  
 4 causation”). This would come into play where a security lost value on news of the  
 5 investigation but then did not respond to a later disclosure by the defendant. In a case  
 6 like that, one can infer that investors interpreted the investigation as a disclosure of fraud  
 7 and thus treated the actual disclosure of fraud as something they already knew. *See, e.g.*,  
 8 *Lloyd*, 811 F.3d at 1210 (finding loss causation where company’s stock dropped 20% on  
 9 news of an SEC subpoena but reacted “hardly at all” to later news that the company’s  
 10 largest borrower was charging off millions in the company’s loans). “[T]he ultimate  
 11 issue is whether the defendant’s misstatement, as opposed to some other fact, foreseeably  
 12 caused the plaintiff’s loss.” *Lloyd*, 811 F.3d at 1210.

13 The complaint alleges that ten different partial corrective disclosures revealing  
 14 false or misleading statements caused losses to Plaintiff as an investor.<sup>5</sup> As a preliminary  
 15 matter, Defendants argue generally that none of the relevant risks was ever concealed;  
 16 risks of government investigations, legal action, negative publicity, and employee  
 17 misconduct were repeatedly disclosed in Insys’s SEC filings. (Doc. 85 at 26.) But none  
 18 of the disclaimers stated in those filings specifically discloses the risk of company-wide  
 19 fraud orchestrated by the company’s highest level executives. That risk was never  
 20 disclosed in any document, much less anything public and available to investors. Since  
 21 that argument is unavailing, the Court must consider one by one whether each alleged  
 22 disclosure is sufficiently pled.

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26       <sup>5</sup> The complaint also raises a second theory known as “materialization of the risk,”  
 27 by which several disclosures reveal fraud to the market gradually over time. *See* Doc. 77,  
 ¶¶ 428-30.) However, at oral argument Plaintiff clarified that he is no longer pursuing  
 28 that argument. The Court will thus only consider the ten corrective disclosures  
 individually.

1                   **a. First and Second Disclosures: November 27, 2014 New York Times  
2 Article and April 24, 2015 Southern Investigative Reporting  
3 Foundation Article**

4                   Defendants argue that the articles published on November 27, 2014, by the New  
5 York Times and April 24, 2015, by the Southern Investigative Reporting Foundation  
6 cannot constitute partial corrective disclosures because they occurred before Plaintiff  
7 purchased Insys stock. (Doc. 85 at 22.) Defendants also argue that the Southern  
8 Investigative Reporting Foundation article merely identifies a government investigation  
9 into Insys that the company had previously disclosed. (Doc. 85 at 22.)

10                  Despite reciting more than 170 pages of allegations against Defendants, the  
11 complaint fails to mention exactly when Plaintiff bought and sold his Insys stock.  
12 However, the record does contain a certification by Plaintiff that he first purchased Insys  
13 stock on May 19, 2015. (Doc. 34-1 at 3.) Indeed, the two articles at issue here were  
14 published before he made any Insys stock purchases. Whether or not these were  
15 corrective disclosures (the Court does not decide that question), they could not have  
16 caused him any loss.

17                  **b. Third and Fourth: May 20, 2015 Indictment of Two Physicians and  
18 June 23, 2015 Guilty Plea of Heather Alfonso (and New York Times  
19 Article Two Days Later)**

20                  Defendants argue that the third partial disclosure, the May 20, 2015 indictment of  
21 two doctors for unlawful distribution of controlled substances, “does not mention Insys,  
22 Subsys, or any off-label marketing or kickback scheme.” (Doc. 85 at 23.) Additionally,  
23 Defendants argue that the complaint does not state any new information disclosed by the  
24 fourth partial disclosure, the June 23, 2015 guilty plea by Heather Alfonso (and the New  
25 York Times article that followed). (Doc. 85 at 23.)

26                  More fundamentally, though, the records of Plaintiff’s stock transactions show that  
27 after purchasing his first batch of Insys stock on May 19, 2015, he sold his stockholdings  
28 on July 8, 2015—for a profit. (Doc. 34-1 at 3.) The next day, he made the purchase of

1 4,000 shares that he currently holds today.<sup>6</sup> (*Id.*) In other words, no corrective  
 2 disclosures, however damning, could have caused Plaintiff any loss before July 9, 2015,  
 3 since he suffered no loss up until that point. These two disclosures are not actionable  
 4 here.

5 **c. Fifth: November 4, 2015 CNBC Article**

6 Defendants argue that the fifth alleged partial disclosure, a November 4, 2015  
 7 article published on CNBC's website, simply revealed that the Department of Health and  
 8 Human Services had recently classified Subsys as commonly prescribed for unintended  
 9 uses but did nothing to reveal securities fraud on the part of Insys. (Doc. 85 at 23-24.)  
 10 Taken in isolation, this would be correct. But by late 2015, allegations against employees  
 11 and collaborating healthcare providers sufficiently saturated the public sphere to create a  
 12 different context for the CNBC article. The public knew Insys faced fraud allegations  
 13 and knew multiple physicians had been charged with accepting bribes or kickbacks in  
 14 exchange for prescribing Subsys. One had even pled guilty. (Doc. 81-4 at 26-35.)  
 15 Against this backdrop, the complaint alleges that the CNBC article lent itself to an  
 16 obvious inference: doctors were overprescribing Subsys because they were getting bribes  
 17 and kickbacks from Insys. The CNBC article did not prove this to be conclusively true.  
 18 But it sufficed to constitute a partial disclosure of the company's underlying fraud.

19 Over the next day, Insys's stock dropped 8.50%. (Doc. 77, ¶ 324.) Plaintiff has  
 20 thus sufficiently pled that the article's new revelations caused a drop in Insys's stock  
 21 price.

22 **d. Sixth: November 5, 2015 Resignation of Babich**

23 Defendants contest Plaintiff's sixth alleged partial disclosure, the November 5,  
 24 2015 announcement of Babich's resignation as CEO, on two separate grounds. First,  
 25 they argue Babich's resignation did not reveal anything more than the fact he was  
 26 resigning. (Doc. 85 at 24.) Second, they argue that either way, announcement of his

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 28 <sup>6</sup> Though it is not in the record, Plaintiff's counsel clarified at oral argument that Plaintiff still owns the shares he purchased on July 9, 2016.

1 resignation caused no loss; Insys's stock price dropped from \$26.38 to \$25.43 between  
 2 November 4 and 5 but then rebounded to \$27.39 by November 6. (*Id.*) For this fact,  
 3 Defendants point the Court to the official Nasdaq website with publicly available records  
 4 of Insys's stock price over time. *See* "Insys Therapeutics, Inc. Common Stock Historical  
 5 Stock Prices," Nasdaq, <http://www.nasdaq.com/symbol/insy/historical> (last visited  
 6 August 1, 2017). While Defendants' reference to these records is not a formal request for  
 7 judicial notice, the Court may take judicial notice of certain facts "on its own." Fed. R.  
 8 Evid. 201(c)(1). Those facts of which it can take notice include anything "not subject to  
 9 reasonable dispute because it . . . can be accurately and readily determined from sources  
 10 whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). Publicly  
 11 traded companies' historical stock prices stand among them. *ScripsAmerica, Inc. v.*  
 12 *Ironridge Global LLC*, 119 F. Supp. 3d 1213, 1232 (C.D. Cal. 2015). Accordingly the  
 13 Court takes judicial notice of Insys's closing stock prices on November 4, 5, and 6, 2015.

14 At least one other circuit has concluded that news of an executive's resignation  
 15 does not by itself amount to a "corrective disclosure," but courts may consider the event  
 16 as "a portion of the totality" that must be considered. *See Pub. Emps. Ret. Sys. of Miss.,*  
 17 *P.R. Teachers Ret. Sys. v. Amedisys, Inc.*, 769 F.3d 313, 322-23 (5th Cir. 2014), *cert.*  
 18 *denied*, 135 S. Ct. 2892 (2015). As the Fifth Circuit pointed out, even a large market  
 19 decline following a high-level resignation "could have simply been a market reaction to  
 20 sudden news that two key executives had left the company." *Id.* at 322. The broader  
 21 context of Babich's announcement makes this a close question because of all the  
 22 allegations swirling in the background. But the significance of Babich's resignation need  
 23 not be determined, because Defendants are correct that Insys's stock experienced no  
 24 actual loss as a result of the announcement. A securities fraud plaintiff must show that he  
 25 "suffer[ed] a loss as a result of the market's reaction." *Oracle*, 627 F.3d at 392. With no  
 26 loss, there can be no loss causation.

27  
 28

1                   **e. Seventh and Eighth: December 3, 2015 and January 25, 2016 Southern**  
 2                   **Investigative Reporting Foundation Articles**

3                   Defendants contend that the seventh and eighth alleged partial disclosures, articles  
 4 from December 3, 2015, and January 25, 2016, published by the Southern Investigative  
 5 Reporting Foundation, merely restated allegations from a separate 2014 securities  
 6 complaint about fraud by the company’s “Prior Authorization Unit” and otherwise leaned  
 7 on unreliable statements by an anonymous source concerning Babich’s resignation.  
 8 (Doc. 85 at 24-25.)

9                   The Court has not taken judicial notice of the 2014 complaint’s contents, and thus  
 10 cannot consider them in deciding this motion. At this stage, Plaintiff’s allegations recited  
 11 in his second amended complaint are assumed to be true unless contradicted by  
 12 something of which the Court has taken notice. The Court therefore assumes that the  
 13 revelations detailed in the Southern Investigative Reporting Foundation articles were  
 14 sufficiently novel to constitute partial disclosures.

15                  By the end of the day on December 3, 2015, Insys’s stock had fallen from \$31.99  
 16 per share to \$26.06 per share from the day before, a drop of 18.54%. (Doc. 77, ¶ 327.)  
 17 The drop on January 25, 2016, was somewhat less dramatic: the stock price fell to \$21.58  
 18 from a price of \$22.65 the previous trading day, a drop of 4.72%. (Doc. 77, ¶ 330.)  
 19 Nonetheless the complaint suffices to plead loss causation as to both of these disclosures.

20                  **f. Ninth: April 11, 2016 Press Release**

21                  Defendants argue that the ninth alleged partial disclosure, an April 11, 2016 press  
 22 release announcing Insys’s lower-than-expected net revenues, “itself does not reveal  
 23 anything about an alleged off-label marketing or kickback scheme.” (Doc. 85 at 25.)

24                  Two Ninth Circuit cases have addressed whether news of a revenue shortfall can  
 25 support loss causation. In *In re Gilead Sciences Sec. Litig.*, 536 F.3d 1049, 1057-58 (9th  
 26 Cir. 2008), the court concluded loss causation was sufficiently pled via allegations that  
 27 news of the defendant pharmaceutical company’s poor quarterly performance caused its  
 28 stock to drop. The complaint in that case accused the company of marketing and selling

1 an HIV drug for off-label uses, which generated between 75% and 95% of all its sales.  
 2 *Id.* at 1051. Several years into these practices, the FDA issued a public Warning Letter  
 3 chastising one of the company's employees for making "oral statements that minimized  
 4 the risk information and broadened the indication for" the drug. *Id.* at 1052-53. After  
 5 quarter upon quarter of reported revenue growth, the company eventually issued a press  
 6 release in late 2003 revealing lower-than-expected sales, which triggered a 12% drop in  
 7 the company's stock. *Id.* at 1054. In concluding the press release sufficed as a public  
 8 disclosure, the court connected the stock drop to the FDA warning letter:

9  
 10 Importantly, the drop occurred immediately after Gilead disclosed less-  
 11 than-expected revenues resulting from the reduction in  
 12 wholesalers' . . . inventories [of the drug], which analysts ascribed to lower  
 13 end-user demand. That lower end-user demand, in turn, is expressly  
 14 alleged to have been caused by the Warning Letter. In this light, the market  
 15 did react immediately to the corrective disclosure—the October 28 press  
 16 release. The Warning Letter, which discussed only two instances of off-  
 17 label marketing, would not necessarily trigger a market reaction because it  
 18 did not contain enough information to significantly undermine Gilead's  
 19 July 2003 pronouncements concerning demand for [the drug].  
 20

21 *Id.* at 1058.

22 However, later in the same year, the Ninth Circuit separately held in *Metzler* that a  
 23 for-profit education company's announcement of lower-than-expected earnings did not  
 24 suffice to establish loss causation. 540 F.3d at 1064. In that case, the complaint alleged  
 25 that the company engaged in a variety of fraudulent practices such as falsifying financial  
 26 aid applications, improperly calculating student enrollment, falsifying student grades, and  
 27 other similar practices in order to maximize the funding it received from the federal  
 28 government. *Id.* at 1055. One of two disclosures the complaint identified as triggering  
 loss to investors was a press release detailing earnings shortfalls that the company  
 attributed to "higher than anticipated attrition" at its schools, which the complaint  
 interpreted as "a euphemism for an admission that they had enrolled students who should

1 not have been signed up at all.” *Id.* at 1059-60. In rejecting this inference, the court  
 2 reasoned that

3  
 4 [s]o long as there is a drop in a stock’s price, a plaintiff will always be able  
 5 to contend that the market “understood” a defendant’s statement  
 6 precipitating a loss as a coded message revealing the fraud. Enabling a  
 7 plaintiff to proceed on such a theory would effectively resurrect what *Dura*  
 8 discredited—that loss causation is established through an allegation that a  
 9 stock was purchased at an inflated price. . . . Loss causation requires more.

10       *Id.* at 1064 (citation omitted).

11       The takeaway from *Metzler* is that “loss causation is not adequately pled unless a  
 12 plaintiff alleges that the market learned of and reacted to the practices the plaintiff  
 13 contends are fraudulent, as opposed to merely reports of the defendant’s poor financial  
 14 health generally.” *Oracle Corp.*, 627 F.3d at 392 (citing *Metzler*, 540 F.3d at 1063). But  
 15 *Gilead* makes clear that just the right causal chain between fraud and a below-  
 16 expectations financial report can suffice to show the market reacted to the fraud rather  
 17 than to the poor results themselves.

18       The allegations here, however, do not establish an adequate causal link. True, the  
 19 second amended complaint does contend that analysts attributed the revenue shortfall to a  
 20 “decline in [prescriptions],” specifically prescriptions “at the lower doses of Subsys,”  
 21 which suggested that “fewer patients were initiating therapy.” (Doc. 77, ¶ 336.) But in  
 22 *Gilead*, the lower end-user demand was “expressly alleged to have been caused by the  
 23 [FDA] Warning Letter,” which stated particular accusations of the company’s fraudulent  
 24 conduct. *Gilead*, 536 F.3d at 1058. By contrast, all the complaint here alleges is that  
 25 news of Insys’s lower revenues “revealed the remaining undisclosed relevant truth  
 26 concealed and/or obscured by Defendants’ prior misstatements and omissions  
 27 surrounding Subsys, including the negative impact on Company revenues that resulted  
 28 from the [Insurance Reimbursement Center’s] decreased ability to obtain third-party  
 payer approval for Subsys prescriptions.” (Doc. 77, ¶ 433.) In other words, Plaintiff here

1 has failed to explicitly connect the decrease in Subsys prescriptions to accusations of  
 2 fraud. It would require several steps of inference to get from fewer third-party-payer  
 3 approvals to the market having learned about Insys's fraudulent practices. Those  
 4 inferences are not explicitly stated in the complaint. The crux of *Gilead* is that a revenue  
 5 shortfall establishes loss causation where the complaint "expressly allege[s]" the requisite  
 6 inferential chain. *Gilead*, 536 F.3d at 1058. That is a perfectly sensible requirement in  
 7 light of the stringent pleading standards of Rule 9(b) and the PSLRA.

8 Given *Metzler*'s resistance to giving mere market loss too much meaning, the  
 9 absence of an expressly alleged connection linking each step of reasoning cannot stand  
 10 on its own. The April 11, 2016 revenue announcement therefore does not suffice to  
 11 establish loss causation.

12 **g. Tenth: December 2016 Indictment**

13 Defendants next contend that the complaint fails to identify how the tenth and  
 14 final partial disclosure, the December 8, 2016 unsealing of an indictment charging  
 15 numerous former Insys executives with racketeering, "identif[ies] with the required  
 16 particularity any alleged misstatement that was rendered untrue by this disclosure."  
 17 (Doc. 85 at 25.) Plaintiff responds only with the general assertion that the indictment  
 18 "revealed additional new facts, including internal Insys communications, demonstrating  
 19 that Defendants deliberately perpetrated the Company-wide and nationwide Off-  
 20 Label/Kickback Scheme and [Insurance Reimbursement Center] Fraud to increase  
 21 Insys's sales revenues." (Doc. 87 at 36.)

22 The question is not whether the indictment "rendered" any statement untrue, but  
 23 whether it revealed to the market that prior statements by Insys and its executives were in  
 24 fact false or misleading. Plaintiff has not adequately alleged that it did. It is not enough  
 25 to say generally that a corrective disclosure "revealed additional new facts" and then  
 26 describe those facts only as "internal Insys communications." To permit that explanation  
 27 would be to dispense with the requirement that securities fraud actions be pled with  
 28 "particularity." Fed. R. Civ. P. 9(b). No defendant could possibly defend themselves

1 against allegations that are so vague. If the December 2016 indictment did reveal  
 2 anything new, Plaintiff has not pled it here.

3 To summarize, only the fifth, seventh, and eighth purported corrective disclosures  
 4 suffice to allege loss causation. The rest either fall outside of when Plaintiff had suffered  
 5 losses or are insufficiently pled to meet the PLSRA pleading standards.

6 **C. 20(a)**

7 Section 20(a) requires both an underlying violation and that the defendant had  
 8 actual power or control over the primary violator. Defendants here challenge the  
 9 complaint only on the grounds that there was no underlying violation of Section 10(b).  
 10 Where a plaintiff fails to plead a violation of 10(b) adequately, a Section 20(a) claim may  
 11 be dismissed summarily. *Zucco*, 552 F.3d at 990. As to Burlakoff, this is the case. The  
 12 claim against him under Section 20(a) is dismissed. But the above discussion makes  
 13 clear that claims under Section 10(b) remain as to all other Defendants. Since  
 14 Defendants challenged the Section 20(a) claim only on that ground, their challenge fails.

15 **IV. SUMMARY**

16 In summary, the Court finds as follows:

- 17 - Only the statements alleged in paragraphs 268 and 272 of the second amended  
 18 complaint meet PLSRA's falsity requirement. All others cannot be part of this  
 19 action.
- 20 - Scienter has been adequately pled as to both Kapoor and Baker.
- 21 - The allegations against Burlakoff are dismissed for failing to meet the "in  
 22 connection with" requirement.
- 23 - Loss causation has been adequately pled only as to the November 4, 2015  
 24 CNBC article, and the December 3, 2015 and January 25, 2016 Southern  
 25 Investigative Reporting Foundation articles. All other alleged "corrective  
 26 disclosures" are no longer part of this action.

1 IT IS THEREFORE ORDERED that Plaintiff's Motion to Dismiss (Doc. 85) is  
2 granted in part and denied in part as summarized in the preceding paragraph.

3 IT IS FURTHER ORDERED that Defendants' Request for Judicial Notice (Doc.  
4 81) is denied to the extent that Defendants ask the Court to take notice of the substantive  
5 content of filings in other judicial proceedings, but granted in all other respects.

6 Dated this 1st day of August, 2017.

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9 Neil V. Wake  
10 Senior United States District Judge

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